

**TAB 21**

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

MDL NO. 1456 / CIVIL ACTION NO. 01-12257-PBS

- - - - - X

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION

- - - - - X

THIS DOCUMENT RELATES TO:

UNITED STATES OF AMERICA, EX REL.  
VEN-A-CARE OF THE FLORIDA KEYS, INC.

vs.

BOEHRINGER INGELHEIM CORPORATION, ET AL.  
CIVIL ACTION NO. 07-10248-PBS

- - - - - X

CAPTIONS CONTINUED ON FOLLOWING PAGES

Videotape deposition of MARK SHAFFER, taken  
pursuant to the Federal Rules of Civil Procedure,  
before Melissa J. Kelly, RPR, CRR, Licensed  
Shorthand Reporter #00307, and Notary Public within  
and for the State of Connecticut, held at the  
Sheraton Danbury Hotel, 18 Old Ridgebury Road,  
Danbury, Connecticut, on May 21, 2008, at 10:09 a.m.

<p style="text-align: right;">46</p> <p>1 What I said at the beginning of the</p> <p>2 deposition is that Roxane's position is that Ven-</p> <p>3 A-Care does not have any independent claims or</p> <p>4 independent rights to ask questions that are not</p> <p>5 related to the government claims and on behalf of</p> <p>6 the government. And so we object to Ven-A-Care's</p> <p>7 lawyers questioning the witness unless it has</p> <p>8 been authorized to do so on behalf of the</p> <p>9 government and in pursuant of the government's</p> <p>10 claims other than original resource-type</p> <p>11 questions.</p> <p>12 So I just wanted to get on the record</p> <p>13 that the government has designated Ven-A-Care to</p> <p>14 take questions in this deposition on behalf of</p> <p>15 the government in pursuit of those claims and</p> <p>16 there won't be duplicative questions between what</p> <p>17 Ven-A-Care's lawyers will be asking of Mr.</p> <p>18 Shaffer and any questions that the government may</p> <p>19 have.</p> <p>20 MS. OBEREMBT: As Roxane knows, we</p> <p>21 believe their position is completely inconsistent</p> <p>22 with explicit statutory language under the false</p>	<p style="text-align: right;">48</p> <p>1 for the record we'll let the proceedings proceed</p> <p>2 with Ven-A-Care's lawyers asking the questions</p> <p>3 subject to our objection that that -- those</p> <p>4 questions would be on behalf of and in pursuit of</p> <p>5 the government's claims other than any original</p> <p>6 source-type questions, which we do believe Ven-A-</p> <p>7 Care has an independent right to ask.</p> <p>8 MR. KILMAN: This is Matt Kilman from</p> <p>9 the State of California. And if I could just</p> <p>10 also put on the record that California cross</p> <p>11 noticed the deposition for the purpose of</p> <p>12 judicial economy and pursuant to the CMO and</p> <p>13 RMVL, and we reserve the right to ask our own</p> <p>14 line of questions.</p> <p>15 MS. RIVERA: Okay.</p> <p>16 MS. POLLACK: Okay.</p> <p>17 MS. ROGERS: And that would be the same</p> <p>18 for the state of Florida.</p> <p>19 MS. RIVERA: Understood.</p> <p>20 BY MS. POLLACK:</p> <p>21 Q. Okay. Mr. Shaffer, we're going to go</p> <p>22 back to the sales meetings in 1994 through 1998.</p>
<p style="text-align: right;">47</p> <p>1 claims act. And the only thing that I wanted to</p> <p>2 say is that we're not going to have duplicative</p> <p>3 questioning of the witness.</p> <p>4 MS. RIVERA: Okay. So you're not</p> <p>5 willing to say that Ven-A-Care has been</p> <p>6 authorized on behalf of the government to ask</p> <p>7 questions on behalf of government claims?</p> <p>8 MS. OBEREMBT: Ven-A-Care is a</p> <p>9 plaintiff in this matter and is such able to ask</p> <p>10 questions both on their own behalf, and in this</p> <p>11 instance we have asked relator's counsel to be</p> <p>12 the lead questioner on this deposition.</p> <p>13 MS. RIVERA: On behalf of both Ven-A-</p> <p>14 Care and the government; is that correct?</p> <p>15 MS. OBEREMBT: If that's a meaningful</p> <p>16 statement to you, you're welcome to make that,</p> <p>17 but Ven-A-Care we believe has an independent</p> <p>18 right to ask questions here.</p> <p>19 In this deposition they will be taking</p> <p>20 the lead, and I do not intend to be asking</p> <p>21 questions.</p> <p>22 MS. RIVERA: Okay. Well, as I said,</p>	<p style="text-align: right;">49</p> <p>1 Did BIPI personnel attend the same</p> <p>2 sales meetings as the Roxane personnel?</p> <p>3 <b>A. No, they did not.</b></p> <p>4 Q. Did you get involved in providing any</p> <p>5 of the materials that were presented at those</p> <p>6 sales meetings in that time frame?</p> <p>7 <b>A. I'm not sure what you mean "involved."</b></p> <p>8 Q. Well, as the area sales manager, would</p> <p>9 you help set the agenda for the meetings?</p> <p>10 <b>A. No.</b></p> <p>11 Q. Who was --</p> <p>12 <b>A. That was set by marketing.</b></p> <p>13 Q. By marketing?</p> <p>14 <b>A. Marketing would set the agenda, right.</b></p> <p>15 Q. Okay. And who would that be? Would</p> <p>16 that be Tom Via or --</p> <p>17 <b>A. Over that time frame there were a</b></p> <p>18 <b>number of different individuals in the marketing</b></p> <p>19 <b>department at Roxane.</b></p> <p>20 Q. Would you make presentations at any of</p> <p>21 these sales meetings?</p> <p>22 <b>A. We would normally at sales meetings</b></p>

14 (Pages 50 to 53)

<p style="text-align: right;">50</p> <p>1 <b>have breakouts with our individual teams, and we</b></p> <p>2 <b>would basically facilitate the meeting.</b></p> <p>3 Q. You wouldn't make presentations to the</p> <p>4 entire group that was --</p> <p>5 <b>A. No. That was basically marketing and</b></p> <p>6 <b>the home office.</b></p> <p>7 Q. Okay. And which home office was that?</p> <p>8 <b>A. Roxane Laboratories.</b></p> <p>9 Q. In your position as the senior area</p> <p>10 sales manager, did you ever get involved with</p> <p>11 pricing of Roxane drugs?</p> <p>12 <b>A. No, I didn't.</b></p> <p>13 MS. RIVERA: Object to form.</p> <p>14 BY MS. POLLACK:</p> <p>15 Q. Who set the pricing for the Roxane</p> <p>16 drugs?</p> <p>17 <b>A. Pricing was set by Roxane, the company.</b></p> <p>18 Q. But what department or group?</p> <p>19 <b>A. I would think marketing set the pricing</b></p> <p>20 <b>or had some say-so in the pricing.</b></p> <p>21 Q. Anybody else involved in that process?</p> <p>22 MS. RIVERA: Object to form.</p>	<p style="text-align: right;">52</p> <p>1 <b>will.</b></p> <p>2 Q. But you said you also and the people</p> <p>3 who worked for you would also call on pharmacies;</p> <p>4 is that correct?</p> <p>5 <b>A. Occasionally, yes.</b></p> <p>6 Q. When you were the area sales manager,</p> <p>7 did you get involved in contracting at all?</p> <p>8 <b>A. No, I didn't.</b></p> <p>9 Q. Did you call on customers like long-</p> <p>10 term care facilities?</p> <p>11 <b>A. I don't recall. At Roxane</b></p> <p>12 <b>Laboratories?</b></p> <p>13 Q. Yes.</p> <p>14 <b>A. I don't recall if we called on long-</b></p> <p>15 <b>term care facilities. I don't think we did.</b></p> <p>16 Q. Did you call on any Hospice customers?</p> <p>17 <b>A. We did call on Hospice.</b></p> <p>18 Q. As part of Roxane?</p> <p>19 <b>A. As part of Roxane.</b></p> <p>20 Q. And that would be to sell the drugs you</p> <p>21 identified earlier?</p> <p>22 <b>A. Yes.</b></p>
<p style="text-align: right;">51</p> <p>1 THE WITNESS: I don't know.</p> <p>2 BY MS. POLLACK:</p> <p>3 Q. Well, as a sales representative, if you</p> <p>4 were out in the field and you learned of a price</p> <p>5 that a competitor was charging for a competitive</p> <p>6 drug, wouldn't you provide that information to</p> <p>7 the marketing folks?</p> <p>8 <b>A. There was communication that would come</b></p> <p>9 <b>back into the home office, yes.</b></p> <p>10 Q. Was that part of your job duties, to</p> <p>11 provide that sort of information if you learned</p> <p>12 it?</p> <p>13 <b>A. Not one of my priorities, no.</b></p> <p>14 Q. But you would do it?</p> <p>15 <b>A. It would depend on the situation.</b></p> <p>16 Q. Okay. Would you direct the people who</p> <p>17 reported to you that if they learned of pricing</p> <p>18 of competitive products to report that back to</p> <p>19 you?</p> <p>20 <b>A. Not really. I mean, our</b></p> <p>21 <b>responsibilities were focused with the physician</b></p> <p>22 <b>in driving prescriptions -- in detailing, if you</b></p>	<p style="text-align: right;">53</p> <p>1 Q. How did marketing interact with the</p> <p>2 sales managers?</p> <p>3 <b>A. At sales meetings, like I mentioned</b></p> <p>4 <b>earlier, there would be interaction. There may</b></p> <p>5 <b>have been occasional conference calls or other</b></p> <p>6 <b>meetings where we might have run into the</b></p> <p>7 <b>marketing folks. But for the most part, as I</b></p> <p>8 <b>mentioned, they were inside at the home office</b></p> <p>9 <b>and we were in the field; so we were separate.</b></p> <p>10 Q. What types of information would they</p> <p>11 provide on these telephone calls?</p> <p>12 <b>A. It could be a vast array of information</b></p> <p>13 <b>on our products, on updates, on promotional</b></p> <p>14 <b>materials, on competitive information.</b></p> <p>15 Q. Would that competitive information</p> <p>16 include the prices that competitors were charging</p> <p>17 for similar drugs?</p> <p>18 <b>A. I don't recall. It could have.</b></p> <p>19 Q. Did you ever get marketing materials</p> <p>20 that talked about the prices your competitors</p> <p>21 were charging for the competitive drugs?</p> <p>22 <b>A. There may have been some, yes.</b></p>

15 (Pages 54 to 57)

<p style="text-align: right;">54</p> <p>1 Q. Was that a pretty regular thing, that</p> <p>2 you would get updates on the competitors' prices?</p> <p>3 A. No. Because I think most of our</p> <p>4 efforts were focused on our activities and our</p> <p>5 messaging with our customer.</p> <p>6 Q. Now, you said in 1999 you became the</p> <p>7 director of palliative care sales; is that</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. What did that entail?</p> <p>11 A. We had started up a new separate sales</p> <p>12 team to continue to call on oncologists and pain</p> <p>13 management physicians along with Hospice,</p> <p>14 basically promoting certain products to</p> <p>15 healthcare professionals to educate them on those</p> <p>16 products for -- to help with palliative care or</p> <p>17 the quality of life in pain control.</p> <p>18 Q. Did you also call on retail pharmacies?</p> <p>19 A. Occasionally we did.</p> <p>20 Q. What percentage of a salesman's efforts</p> <p>21 would you say were spent calling on retail</p> <p>22 pharmacies?</p>	<p style="text-align: right;">56</p> <p>1 Q. Were there any interim meetings of the</p> <p>2 area managers?</p> <p>3 A. No. Because our territories were so</p> <p>4 large.</p> <p>5 Q. During the time that you were the</p> <p>6 senior area sales manager, did Roxane launch any</p> <p>7 new drugs?</p> <p>8 MS. RIVERA: Object to form.</p> <p>9 THE WITNESS: As I had mentioned</p> <p>10 earlier, Viramune was a new drug that we</p> <p>11 launched.</p> <p>12 BY MS. POLLACK:</p> <p>13 Q. Anything else besides Viramune?</p> <p>14 A. I can't recall.</p> <p>15 Q. Was there a separate launch meeting to</p> <p>16 talk about Viramune?</p> <p>17 A. I believe there was.</p> <p>18 Q. And did that meeting include training</p> <p>19 materials for the sales representatives?</p> <p>20 A. I believe it did.</p> <p>21 Q. Would there be presentations made by</p> <p>22 various people to talk about the drug?</p>
<p style="text-align: right;">55</p> <p>1 A. Fifteen, maybe 20 percent.</p> <p>2 Q. Now, what drugs were sold by this</p> <p>3 palliative care group?</p> <p>4 A. Roxanol, Oramorph SR, Marinol and I</p> <p>5 believe Roxicodone.</p> <p>6 Q. Did you also sell a drug called</p> <p>7 Duraclon?</p> <p>8 A. We did sell Duraclon for a short period</p> <p>9 of time.</p> <p>10 Q. Any other drugs that you can recall?</p> <p>11 A. I can't recall any other drugs.</p> <p>12 Q. Roxanol, Roxanol T, was that a drug</p> <p>13 that you sold in this group?</p> <p>14 A. Yes. Roxanol T was very similar to</p> <p>15 Roxanol.</p> <p>16 Q. And did this group also have sales</p> <p>17 meetings of the type we discussed earlier?</p> <p>18 A. Yes, we did.</p> <p>19 Q. Were they quarterly; was there any set</p> <p>20 time frame?</p> <p>21 A. I don't recall. I want to think they</p> <p>22 were three times a year.</p>	<p style="text-align: right;">57</p> <p>1 A. As with most sales meetings, yes.</p> <p>2 Q. Were there any drugs launched while you</p> <p>3 were head of the palliative care group?</p> <p>4 A. There was an extension of Roxicodone</p> <p>5 that was launched on different strengths.</p> <p>6 Q. And that was the 15 milligram and the</p> <p>7 30 milligram tablets?</p> <p>8 A. Yes.</p> <p>9 Q. Were those drugs launched pursuant to a</p> <p>10 new drug application that had been filed by</p> <p>11 Roxane?</p> <p>12 A. I don't recall. I'm not sure.</p> <p>13 Q. Were there any clinical trials done in</p> <p>14 connection with those two new products?</p> <p>15 A. I don't recall.</p> <p>16 Q. You don't know. It's possible?</p> <p>17 A. There may have been. I don't recall.</p> <p>18 Q. Now, you said in 2000 Roxane divested</p> <p>19 the palliative care drugs; is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Do you know why that occurred?</p> <p>22 A. I do not know why we basically divested</p>

57 (Pages 222 to 225)

<p style="text-align: right;">222</p> <p>1 MS. RIVERA: Object to form.</p> <p>2 THE WITNESS: Right.</p> <p>3 MS. RIVERA: What do you mean by</p> <p>4 "Boehringer Ingelheim"?</p> <p>5 BY MS. POLLACK:</p> <p>6 Q. The Boehringer Ingelheim worldwide</p> <p>7 organization, right?</p> <p>8 MS. RIVERA: Object to form.</p> <p>9 BY MS. POLLACK:</p> <p>10 Q. You can answer.</p> <p>11 <b>A. It's part of Boehringer Ingelheim.</b></p> <p>12 Q. In fact, all the stationery says right</p> <p>13 in the upper right-hand corner "Boehringer</p> <p>14 Ingelheim"; isn't that correct?</p> <p>15 <b>A. I'm not sure which stationery you're</b></p> <p>16 <b>referring to.</b></p> <p>17 Q. Okay. You can look at the documents we</p> <p>18 looked at today.</p> <p>19 Okay. If you look at page 29, it lists</p> <p>20 the key strategies; and the first one is "target</p> <p>21 distribution to high-volume C2 analgesic</p> <p>22 pharmacies," correct?</p>	<p style="text-align: right;">224</p> <p>1 THE WITNESS: Again, that's -- you keep</p> <p>2 bringing that up, and that's not how I'm looking</p> <p>3 at it.</p> <p>4 BY MS. POLLACK:</p> <p>5 Q. How are you looking at it?</p> <p>6 <b>A. I'm looking at it that the product was</b></p> <p>7 <b>priced so pharmacies would bring the product in</b></p> <p>8 <b>and we would not be substituted because of the</b></p> <p>9 <b>new 15 and 30 milligram strengths being available</b></p> <p>10 <b>and prescriptions are being driven.</b></p> <p>11 Q. Okay. Now, Roxane at that time</p> <p>12 manufactured and sold a 5 milligram Roxicodone</p> <p>13 tablet; is that correct?</p> <p>14 <b>A. Yes, correct.</b></p> <p>15 Q. So you could have been substituted with</p> <p>16 the Roxane product under your scenario, correct?</p> <p>17 <b>A. It could have been, yes.</b></p> <p>18 Q. Okay. Now we get to page 35 which is</p> <p>19 also Shaffer 1486, and this outlines the pricing</p> <p>20 approach, doesn't it?</p> <p>21 <b>A. That's what the document says, "pricing</b></p> <p>22 <b>approach."</b></p>
<p style="text-align: right;">223</p> <p>1 <b>A. Correct.</b></p> <p>2 Q. That's what you just mentioned, is to</p> <p>3 get the product into the pharmacies, right?</p> <p>4 <b>A. Yup.</b></p> <p>5 MS. RIVERA: Sorry. What page are you</p> <p>6 on?</p> <p>7 MS. POLLACK: 1480. It's 29.</p> <p>8 MS. RIVERA: Okay. Thank you.</p> <p>9 BY MS. POLLACK:</p> <p>10 Q. And also listed is price for favorable</p> <p>11 retail reimbursement, correct?</p> <p>12 MS. RIVERA: Object to form. What is</p> <p>13 the question? That's what it says?</p> <p>14 BY MS. POLLACK:</p> <p>15 Q. I'm asking: One of the key strategies</p> <p>16 listed here was price for favorable retail</p> <p>17 reimbursement?</p> <p>18 <b>A. That's what it has on here, yes.</b></p> <p>19 Q. And that was to provide more profit to</p> <p>20 the pharmacy to fill a prescription with the 15</p> <p>21 and 30 milligrams, correct?</p> <p>22 MS. RIVERA: Object to form.</p>	<p style="text-align: right;">225</p> <p>1 Q. Okay. And it says, "Set AWP and WAC at</p> <p>2 a level favorable to the average for oxycodone</p> <p>3 class for equivalent number of 5 milligram</p> <p>4 tablets," right?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. "Equivalent or higher reimbursement</p> <p>7 levels, AWP minus a percentage."</p> <p>8 <b>A. That's what it says.</b></p> <p>9 Q. And "minimal need for contract</p> <p>10 pricing"?</p> <p>11 <b>A. That's what it says, yes.</b></p> <p>12 Q. Wasn't in fact -- weren't in fact these</p> <p>13 two strengths sold at contract prices to GPOs?</p> <p>14 <b>A. I don't recall. I -- because the</b></p> <p>15 <b>product was only on the market for several</b></p> <p>16 <b>months, and I don't recall if we put that on</b></p> <p>17 <b>contracts or not.</b></p> <p>18 Q. Well, wasn't the product on the market</p> <p>19 for at least a year?</p> <p>20 <b>A. It may have been. Let me rephrase my</b></p> <p>21 <b>comment.</b></p> <p>22 <b>It was -- while we were at Roxane</b></p>

<p style="text-align: right;">226</p> <p>1 <b>Laboratories, that fall the division was</b>  2 <b>dissolved, I believe, in November. So our</b>  3 <b>activity was limited to two months, I believe,</b>  4 <b>with this product.</b>  5 Q. November or at the end of the year that  6 the division was --  7 A. I think it was in -- at the end of  8 November.  9 Q. Okay. If you look at page 1489, it  10 says: "For contracting, limit discounts to a  11 maximum of 10 percent to provide an incentive to  12 substitute 15 milligram for three 5 milligram or  13 30 milligram for six 5 milligram."  14 Does that indicate that the contract  15 price would be up to 10 percent off the WAC?  16 A. Again, I wasn't involved with pricing.  17 I don't recall the contract pricing.  18 Q. And the other bullet on this point  19 says: "Select only accounts that can move market  20 share."  21 What does that mean?  22 A. I'm not sure what that bullet point</p>	<p style="text-align: right;">228</p> <p>1 Q. And the goal, of course, was to  2 increase your market share, right? That's what  3 the sales force was supposed to do?  4 A. I think that's a fair statement.  5 Q. How was the sales force compensated?  6 A. We were compensated, like a lot of  7 pharmaceutical companies, by bonuses. I believe  8 we were on a quarterly basis based on goal  9 attainment, quota attainment.  10 Q. And when you say "bonus," was that a  11 commission or --  12 A. It was an extra bonus commission.  13 Q. Based on amount of sales; is that what  14 you're saying?  15 A. Based on goal attainment, yes.  16 Q. Was that an increase in sales over last  17 year? How was that calculated?  18 A. I don't recall. I wasn't involved with  19 setting of those goals.  20 Q. But you had one every year?  21 A. Absolutely.  22 Q. And as the manager of the palliative</p>
<p style="text-align: right;">227</p> <p>1 means under "strategy."  2 Q. Was market share a concept that was  3 discussed at the palliative care sales meetings?  4 A. I don't recall. I mean, other than  5 your initial slides from marketing talking  6 historically about the product and the growth of  7 the product, trends of the product in share,  8 other than that, I don't recall.  9 Q. So you would look at what percent of  10 the coating market was sold by Roxane and sold by  11 Purdue Frederick or other competitors; is that  12 correct?  13 A. Yes.  14 Q. And then you would break it down to  15 each of the codone products that were sold by  16 Roxane, what percentage product had of the total  17 market?  18 A. I don't believe the specific -- I don't  19 remember the specifics with the breakdown, but  20 that's --  21 Q. The type of thing you looked at.  22 A. -- the type of thing.</p>	<p style="text-align: right;">229</p> <p>1 care sales force, you had one too, correct?  2 A. I don't recall my -- what my plan was  3 like compared to the sales representatives  4 specifically.  5 Q. When the sales representatives got  6 these bonuses, were there occasions where a  7 portion of their bonus was based on selling a  8 particular drug as opposed to the total sales  9 that they were responsible for?  10 A. Yes. The bonuses -- the plans were set  11 up according to promote a product.  12 Q. So some years Roxane would be promoting  13 product X more than maybe the rest of the product  14 line?  15 A. Yes.  16 Q. And page 39 indicates as part of the  17 pricing strategy was "a Medicaid reimbursement  18 plan which included submitting requests for the  19 Roxicodone 15 and 30 milligram tablets to be  20 added to state Medicaid formularies." Do you see  21 that?  22 A. I see it on here.</p>